Quality Improvement in Extracorporeal Photopheresis

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Disclosures

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Objectives

• Review mechanism of action in ECP
• Discuss basic concepts of quality improvement
• Describe areas of variability that may affect patient outcomes
• Provide methods to monitor these areas
• Discuss solutions to common problems
The Basics

Extracorporeal Photopheresis (ECP)

The photoactivated white blood cells are returned to the patient

The THERAKOS® UVAR® XTS® instrument draws blood from the patient

Blood is separated by centrifugation and red blood cells are returned

White blood cells are treated with Methoxsalen Sterile Solution and exposed to UVA light

Photoactivation with UVA light

Methoxsalen
ECP Mechanism of Action

Quality Improvement

- Perform Procedure
- Evaluate
- Assess Variability
- Plan
- Improve

[Diagram showing the cycle of quality improvement with labels for each step: Perform Procedure, Evaluate, Assess Variability, Plan, Improve]
Quality Improvement

- Reviewed the Basics

Perform Procedure

Evaluate

Assess Variability

Plan

Improve
Evaluate

• Patient outcomes
  – Clinical improvement
  – Decreases in immunosuppressant medications
    • GVHD or solid organ transplant rejection
Evaluate

• Collected product
## Quality control practices

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you routinely perform quality control assessment of the collected ECP product using any laboratory parameters?</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>41 (34%)</td>
</tr>
<tr>
<td>No</td>
<td>80 (66%)</td>
</tr>
</tbody>
</table>

Data obtained from the ASFA ECP Subcommittee
# Quality Control Measures

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which of the following laboratory parameters on the collected ECP product are routinely assessed? (N=41)</td>
<td></td>
</tr>
<tr>
<td>Total cell count</td>
<td>34 (83%)</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>31 (76%)</td>
</tr>
<tr>
<td>Lymphocyte count</td>
<td>30 (73%)</td>
</tr>
<tr>
<td>Monocyte count</td>
<td>25 (61%)</td>
</tr>
<tr>
<td>Bacterial culture</td>
<td>10 (24%)</td>
</tr>
<tr>
<td>Flow cytometric assay</td>
<td>5 (12%)</td>
</tr>
<tr>
<td>Apoptosis assay</td>
<td>4 (10%)</td>
</tr>
<tr>
<td>Evaluation of cell populations</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>Proliferation assays</td>
<td>3 (7%)</td>
</tr>
</tbody>
</table>

Data obtained from the ASFA ECP Subcommittee
Collected Product

• WBC, Lymphocytes, Monocytes
  – Fold enrichment
  – Percentage of cells treated
Collection efficiencies

• Evaluated relationships between peripheral blood counts and buffy coats

• Assess collection efficiency by
  – Fold enrichment
    • The ratio of cells in buffy coat to those in peripheral blood
  – Percentage of total cells collected during leukapheresis

Collection efficiencies

Quality Improvement

- Reviewed the Basics

- Patient Outcomes
  - Collected Product

Perform Procedure

Evaluate

Assess Variability

Plan

Improve
Areas of Variability

Collected Product

- Operator/Organization
- Patient Access
- Whole Blood Processed
- Hematocrit
- Cell counts
- Machine
Patient Access

• Variety of central lines, peripheral IVs, and AV fistulas

• Evaluation/Problem
  – Frequency of tPA
  – Pressure alarms

• Solutions
  – tPA
  – Exchange line
  – Set a preference
Whole Blood Processing Amount

• Standard 1500 mL (500-2000mL)
• Problem/Evaluation
  – Alarms limiting collection
  – Treatment volume
• Solutions
  – Individual alarms
  – Increase WBP
Mini-photopheresis

• Patients with low body weight or contraindications to apheresis
• Mini-photopheresis treatments
  – Patients > 20 kg - 200 mL of whole blood
  – Patients < 20 kg - 100 to 150 mL

Mini-photopheresis

Whole Blood Processing

• How much is enough?
PCH Research Protocol

- A prospective study of blood processing amounts in pediatric GVHD patients
  - Comparing 1500 mL WBP amount with 1250 mL
    - Percentage of cells treated
    - Fold enrichment
    - Clinical outcomes
    - T-cell markers
Hematocrit

• Initial Hematocrit
• Evaluation/Problem
  – Time to interface
• Solution
  – Blood Prime
Initial Blood Counts

• White blood cells, lymphocytes, monocytes
• Evaluation/Problem
  – Decrease in cell fold enrichment
• Solution
  – Hold procedure for WBC < 500, < 1000, etc.
Machine

• Variables
  – Flow rates
  – UVA exposure
  – Intra-device cellular interactions

• Forgiving process
Operator

• Different levels of experience
• Problem/Evaluation
  – Alarms
  – Hematocrit in treatment bag
  – Length of UVA treatment
  – Interface adjustments
Operator

• Solution
  – Education
  – Staffing
  – Documentation
  – Improving communication
Quality Improvement Summary

- Reviewed the Basics
- Patient Outcomes
- Collected Product
- Areas of Variability

QUALITY IMPROVEMENT

Perfom Procedure

Evaluate

Assess

Plan

Improve

Solutions

**QUALITY **

**IMPROVEMENT**
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